

Serial No: 10/618,977

PATENT

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claims 1-34. (Cancelled).

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Please enter the following new claims.

- 1 35. (New) A method of delivering a lipophilic bioactive material to an
- 2 interior wall of a body vessel from an implantable medical device having an
- 3 expandable balloon with the lipophilic bioactive material on an outer surface of
- 4 the balloon, the method comprising the steps of:
- 5 inserting the balloon into a body vessel, the balloon being free of: a
- 6 coating atop the bioactive material, a time-release layer, a containment
- 7 material and a containment layer;
- 8 advancing the balloon within the body vessel to a treatment site
- 9 within the body vessel;
- 10 inflating the balloon at the treatment site to contact the bioactive
- 11 material with an inner wall of the body vessel;
- 12 maintaining the bioactive material on the outer surface of the
- 13 inflated balloon in contact with the inner wall of the body vessel while the
- 14 balloon is inflated;
- 15 deflating the balloon after contacting the bioactive material with the
- 16 inner wall of the body vessel; and
- 17 removing the deflated balloon from the body vessel.

- 1 36. (New) The method of claim 35, wherein the balloon is inflated at the
- 2 treatment site with an inflation time of up to about one minute.

Serial No. 10/618,977

PATENT

- 1 37. (New) The method of claim 35, wherein the bioactive material  
2 comprises paclitaxel or a paclitaxel derivative.
- 1 38. (New) The method of claim 37, wherein the bioactive material further  
2 comprises a diagnostic agent.
- 1 39. (New) The method of claim 35, wherein the body vessel is a blood  
2 vessel.
- 1 40. (New) The method of claim 39, wherein the body vessel is a coronary  
2 artery.
- 1 41. (New) The method of claim 35, wherein the implantable medical  
2 device includes a total of about 5 to about 500 micrograms of the lipophilic  
3 bioactive material on the outer surface of the balloon prior to inserting the  
4 medical device into the body vessel.
- 1 42. (New) The method of claim 35, wherein the method is performed  
2 without implanting a stent within the body vessel.
- 1 43. (New) The method of claim 35, wherein the balloon comprises a  
2 material selected from the group consisting of: a polyamide, polypropylene,  
3 polyether block amide and polyethylene.
- 1 44. (New) The method of claim 35, wherein the implantable medical  
2 device is a balloon catheter coated with a single layer of the lipophilic bioactive  
3 material on the balloon, the single layer consisting essentially of about 5 to  
4 about 500 micrograms of paclitaxel or a paclitaxel derivative deposited on the  
5 outer surface of the expandable balloon.

Serial No. 10/618,977

PATENT

1 45. (New) The method of claim 35, wherein the lipophilic bioactive  
2 material is transferred from the outer surface of the Inflated balloon to the  
3 inner wall of the body vessel while contacting the outer surface of the inflated  
4 balloon with the inner wall of the body vessel.

1 46. (New) The method of claim 35, wherein the implantable medical  
2 device is a balloon catheter having an expandable balloon with about 0.2 to  
3 about 20 micrograms of paclitaxel or a paclitaxel derivative deposited per mm<sup>2</sup>  
4 of the outer surface of the expandable balloon and a total of about 5 to about  
5 500 micrograms of the paclitaxel or the paclitaxel derivative deposited on the  
6 outer surface of the expandable balloon; and wherein the method further  
7 includes at least one of:  
8 percutaneous insertion of the expandable balloon into a blood  
9 vessel;  
10 inflation of the balloon at the treatment site with an inflation time of  
11 up to about one minute to contact the paclitaxel or the paclitaxel derivative  
12 with the inner wall of the body vessel; or  
13 maintaining the outer surface of the inflated balloon in contact with  
14 the inner wall of the body vessel for up to about 20 minutes.

1 47. (New) The method of claim 35, wherein  
2 the implantable medical device is a balloon catheter having an  
3 expandable balloon with a total of about 5 to about 500 micrograms of paclitaxel  
4 or a paclitaxel derivative deposited on the outer surface of the expandable  
5 balloon;  
6 the expandable balloon is percutaneously inserted into a blood  
7 vessel;  
8 the balloon is inflated at the treatment site with an inflation time of  
9 up to about one minute to contact the paclitaxel or paclitaxel derivative with  
10 the inner wall of the body vessel; and

Serial No. 10/618,977

PATENT

1           the outer surface of the inflated balloon is maintained in contact with  
2   the inner wall of the body vessel for up to about 20 minutes.

1   48. (New)           The method of claim 35, wherein the implantable medical  
2   device is a balloon catheter having an expandable balloon with a total of about  
3   0.2 to about 20 micrograms of paclitaxel or a paclitaxel derivative per mm<sup>2</sup> of  
4   the outer surface of the expandable balloon before inserting the balloon into  
5   the body vessel.